



PCT 4

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: ) Confirmation No.: 4282  
Kenshi KAMEI et al )  
Appln. No.: 10/532,585 ) Art Unit: 1614  
Filing Date: 10/24/2003 ) Examiner: P. G. Spivack  
371(c) Date: 04/25/2005 )  
For: THERAPEUTIC AND/OR ) September 29, 2006  
PREVENTIVE AGENT... ) ATTY.'S DOCKET: KAMEI=2  
)

INFORMATION DISCLOSURE STATEMENT [IDS]

Customer Service Window, Mail Stop Amendment  
Honorable Commissioner for Patents  
U.S. Patent and Trademark Office  
Randolph Building, 401 Dulany Street  
Alexandria, Virginia 22314

Sir:

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed:

[ ] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.

[ ] B. before the mailing date of a first office action on the merits or before the mailing of a first Office action after the filing of a Request for Continued Examination under 37 CFR §1.114; or

[x] C. after (A) and (B) above, but before final rejection or allowance, and Applicant has made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below):

[ ] i. Counsel certifies that, upon information and belief, each item of information listed herein either was

[ ] (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

[ ] (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, not known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this IDS.

[x] ii. Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in 37 CFR §1.17(p), presently believed to be \$180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035 of the undersigned.

2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., form BN/SB/08A/B) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. Other than U.S. patent(s) and/or published U.S. application(s), which 37 CFR §1.98(a)(2)(ii) does not require to be filed unless specifically required by the Office, a copy of each document listed is attached.

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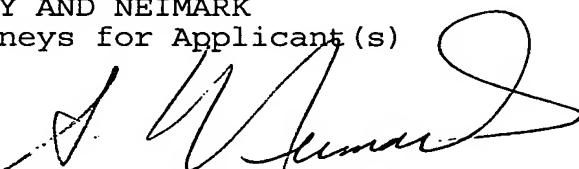
3. o explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

4. n accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in 37 CFR §1.56(b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

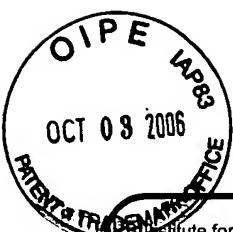
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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of

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## Complete if Known

Application Number	10/532,585
Filing Date	April 25, 2005
First Named Inventor	K. KAMEI et al
Group Art Unit	1614
Confirmation No.	4282

Attorney Docket Number

KAMEI=2

## NON PATENT LITERATURE DOCUMENTS / OTHER INFORMATION

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	AK	O. ALARADI et al; "Irritable bowel syndrome: update on pathogenesis and management"; <i>Med Principles Pract</i> ; Vol. 11, page 2-17, 2002.	
	AL	M. BRADETTE, et al; "Effect of motilin and erythromycin on the motor activity of the human colon"; <i>J. Gastrointest. Mot.</i> , Vol. 5, pages 247-251, 1993.	
	AM	D. M. CHIEPPA, et al; Effects of erythromycin on human colonic circular muscle in idiopathic chronic constipation", <i>European Journal of Clinical Investigation</i> ; Vol. 30, pages 66-71, 2000.	
	AN	D. HARARI et al; "Correlates of regular laxative use by frail elderly persons"; <i>The American Journal of Medicine</i> , Vol. 99, pp. 513-518,	
	AO	Zen ITOH; "Motilin and Clinical Application"; <i>Peptides</i> , Vol. 18, No. 4, pages 593-608, 1997.	
	AP	J. S. JAMESON et al; "Oral or intravenous erythromycin has no effect on human distal colonic motility"; <i>Aliment. Pharmacol. Ther.</i> , Vol. 6, pages 589-595, 1992.	
	AQ	I.M.C. KAMERLING et al; "Dose-related effects of motilin on proximal gastrointestinal motility"; <i>Aliment Pharmacol Ther</i> ; Vol. 16, pages 129-135, 2002.	
	AR	I.M.C. KAMERLING et al; "Exogenous motilin affects postprandial proximal gastric motor function and visceral sensation"; <i>Digestive Diseases and Sciences</i> ; Vol. 47, No. 8, pages 1732-1736, 2002.	
	AS	H. KOGA et al; "Design, SAR and pharmacology of GM-611, the first acid-stable non-peptide motilin receptor agonist"; <i>Drugs of the Future</i> ; Vol. 27, No. 3; pages 255-272, 2002.	
	AT	Y.C. LUIKING et al; "Motilin induces gall bladder emptying and antral contractions in the fasted state in humans"; <i>Gut</i> ; Vol. 42, pages 83-835, 1998.	
	AU	M. PAPPAGALLO: "Incidence, Prevalence, and Management of Opioid Bowel Dysfunction"; <i>The American Journal of Surgery</i> ; Vol. 182, pages 11S-18S; 2001.	
	AV	S. SHARMA et al "Effect of oral erythromycin on colonic transit in patients with idiopathic constipation"; <i>Digestive Diseases and Sciences</i> , Vol. 40, No. 11, pages 2446-2449, 1995.	
	AW	D. THORPE; "Management of Opioid-induced Constipation"; <i>Curr. Pain Headache Rep.</i> , Vol. 5, pages 237-240, 2001.	

Examiner Signature	Date Considered
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\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.